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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/084,855      | 02/27/2002  | Evan C. Ungcr        | UNGR-1632           | 8641             |

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/084,855

Applicant(s)

UNGER, EVAN C.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,47,49-51 and 55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,47,49-51 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Amendment filed on January 9, 2006 has been entered. Claims 1, 47, 49-51, 55 are pending.

Any rejection that is not addressed in this Office Action is considered obviated in view of the amendments. However, the claims are now directed to a new grounds of rejection as necessitated by the Amendment.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 47, 49-51, 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grinstaff et al US Patent 5,498,421 in view of Ottoboni et al US Patent 6,193,951, Unger et al and Hirota US Patent 4,960,595.

Ottoboni teaches bi-layered shell microspheres containing an outer shell and an inner shell, wherein the outer layer will be a biologically compatible material and the inner layer will be a biodegradable polymer tailored to form a core that contains a gas and can further provide drug delivery properties (see col 2, lines 44-67). Ottoboni teaches that the inner layer comprise an organic liquid core that falls within the limitation of the instantly recited oil. (see col 8, lines 1-67). Ottoboni fails to specifically employ a lipid component such as a phosphatidic acid in his microspheres.

Grinstaff teaches that polymeric shells may be modified with phospholipids to form a stabilize lipid containing microspheres (see claim 26). In fact, Grinstaff teaches similar microspheres as Ottoboni, except that it comprise a biologic agent, a polymeric

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shell encapsulating a perfluorocarbon gas. (see col 12, lines 10-40; example 13, 35-37, claims 1, 12-13). Grinstaff only fails to articulate the use of a phosphatidic acid as a lipidic moiety.

The teachings of Unger and Hirato are previously described.

Unger teaches phosphatidic acid containing microspheres. Unger teaches delivery systems comprising gas filled liposomes containing a bioactive agent, and an oil (see abstract, col 21, line 20-col 22, lines 9-67). The delivery systems of Unger contains one or more phospholipids selected from group phosphatidic acid, phosphatidylcholine, phosphatidylethanolamines, perfluorocarbon, and a suitable oils such as glyceryl monostearate, corn oil, olive oil, mineral oil etc... (see col 13, lines 30-45; col 8, lines 10-21; 32, lines 55-65; col 33, lines 5-10).

Hirato explicitly says that phosphatidic acid is an auxiliary material that stabilizes dispersions of lipidic microspheres (see col 3, lines 20-44).

Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to employ at least one lipidic components of Unger in the microspheres of Ottoboni to provide effective drug delivery systems, because as described by Grinstaff, polymeric shells can be modified to contain phospholipids and as evidenced by Unger and as described by Hirato, phosphatidic acid improves the stability of such microspheres. One of ordinary skill in the art would have been motivated to do such modifications because, as described by Grinstaff, polymeric shells and their phospholipids modified analogs are art recognized functional equivalents. Further, the use of phosphatidic acid is conventionally practiced to improve the stability of such

micropsheres. Accordingly, the combination of the cited references render the instant claims obvious as it teaches all elements of the instant claims.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SS



**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**